UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUL 29 1994

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

DECISION MEMORANDUM

SUBJECT: Unconditional, One Year Registration of New Biochemical and Reduced Data Active Ingredient, Castor Oil (USP Grade), and End-Use Product

FROM: Stephen Johnson, Director
Registration Division (H-7505C)

Lois Rossi

TO: Dan Barolo, Director
Office of Pesticide Programs (H-7501C)

The purpose of this memorandum is to request your concurrence with my recommendation for a one year, unconditional registration of Mole-Med, EPA File Symbol 64439-R, which contains a new Biochemical, Castor Oil (USP Grade) and a reduced (low risk) data set.

As background for your decision, I briefly describe the use pattern, regulatory history, and a pending regulatory action for Mole-Med and summarize the science findings and reason for making this registration unconditional for one year.

BACKGROUND

Use Pattern

The purpose of the product is to repel moles from lawns. The applicator mixes 1 oz of Mole-Med to 1 gallon of water and then applies this quantity of diluted product to 312 sq. ft. (10 and 30 feet) to a lawn with active tunnels. The applicator uses a hand-held sprayer or sprinkling can to apply the diluted product and then waters in the product for 25 minutes.

Regulatory History

On **December 4, 1990**, the Agency received an application to register the mole repellent, Mole-Med. Initially, the registrant and the Agency assumed that this application constituted a **new use of an old chemical.** However, we soon learned that all previously registered products containing Castor Oil had already been cancelled. Therefore, the Agency considered this active ingredient as **new** and subject to all the requirements of the Federal Insecticide, Fungicide, and Rodenticide Act.

Following additional communications with the registrant, the Agency, on its own initiative, reviewed this active to determine if it should be a **conventional pesticide** or **biochemical.** On **March 11, 1992,** we informed the registrant that the Agency now considered Castor Oil to be a **biochemical** and provided the Company with a **revised and reduced list of data requirements,** which **still required an efficacy test but eliminated all environmental fate tests, one avian dietary test, and one freshwater fish test.**

Science Findings

During the screening of the application, the **Agency further reduced the data requirements** to include waiver of **certain chemistry data for Castor Oil and Mole-Med, all acute toxicity data for Castor Oil, three acute toxicity tests for Mole-Med, and all remaining ecological effects data.** The Agency believes that the reduced data set is appropriate because of minimum exposure and toxicity to humans, lack of adverse data, minimum exposure to birds, FDA approval as a food additive and medicine, low solubility, and the registrant's williness **to use United States Pharmacopeia (USP) grade Castor Oil and to amend its label** to mitigate certain possible environmental hazards. A complete discussion of the rationale for reducing the data requirements may be found in the attached memorandum dated March 9, 1993.

The Agency's reviews of the product chemistry, acute toxicology, and efficacy have been completed. With the exception of efficacy, all the data are complete. **The available data support an unconditional, one year registration Mole-Med.** A summary of the science findings is provided below.

1. Chemical Characteristics [40 CFR 158.690(a)]:

Castor Oil is derived from the seeds of the castor bean plant. The registrant only uses the USP grade of Castor Oil, which the Food and Drug Administration (FDA) has found acceptable 1) for pharmaceutical use and 2) as a direct food additive under its regulations (21 CFR 172.876). Therefore, the Agency only needs the basic information about the identity, analytical methods, and physical and chemical properties of Castor Oil and Mole-Med supplied by the registrant.

2. Toxicological Characteristics [40 CFR 158.690(c)]:

Because of minimum exposure and toxicity to humans, FDA approval as a food additive and medicine if USP grade is used, and lack of adverse data and effects in the literature, the

Agency only required acute toxicology data on the end-use, Mole-Med:

Test Name	Results	Toxicity Category
a. Acute Oral (151A-10)	>5gm/kg	IV (CAUTION)
b. Primary Eye Irritation (151A-13)	Moderate irritation reversible in 7 days	II (WARNING)
c. Primary Dermal Irritation (151A-14)	Variable erythema and slight edema	III (CAUTION)

3. Environmental Fate Characteristics [40 CFR 158.690(d)]:

The Agency has agreed that Castor Oil meets the criteria for a biochemical: non-toxic mode of action, natural occurrence, low use volume, and target species specificity. Therefore, for the intended use pattern, the Agency does not normally require such actives to be supported by fate data, unless another study indicates a problem. The Agency has no such problem study.

4. Ecological Effects [40 CFR 158.690(d)]:

The Agency is not requiring any tests because of the minimum exposure to birds, lack of rat oral toxicity, FDA approval as a food additive and medicine (if USP grade), and low solubility. **To mitigate any possible risks to aquatic organisms**, we will require the following labeling changes:

a. If product is intended for **outdoor, domestic use only**, the registrant will be required to add the following "ENVIRONMENTAL HAZARDS" statement:

ENVIRONMENTAL HAZARDS

Do not apply directly to water.

b. If product is also intended for **outdoor, non-domestic use**, the registrant will be required to add the following "ENVIRONMENTAL HAZARDS" statement:

ENVIRONMENTAL HAZARDS

Do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters.

c. The registrant will also be required to make the following change in the "DIRECTIONS FOR USE":

> Change "Then water in for 25 minutes." to "Then soak in with water for about 25 minutes. Avoid using excess water that may flow off turf into streams, ponds, gutters or storm sewers."

5. Performance Characteristics [40 CFR 158.640]:

The first efficacy tests were not scientifically valid, and the Company possibly submitted fraudulent information about the study director and her qualifications. The Team passed this information to Region 5, which notified the Justice Department, who after an investigation declined to pursue.

Subsequently, the Company submitted new efficacy tests, which were difficult to interpret because the study was truncated prematurely because the registrant did not pay the researchers, Nevertheless, **the Agency is hoping to obtain additional data this summer from these same researchers who are doing some additional tests on their own to resolve some questions raised by the incomplete studies.**

Over the past four and half years, this pending application has generated a number of **Congressional inquiries.** Most concerned the need for such a small company to address all the data requirements of a new active ingredient, when the product has been used as an over the counter drug for a long time and even recommended in the organic gardening literature. Such inquiries made the Agency re-evaluate its past policy of requiring registrants of low risk actives to develop waivers for all the normal requirements of a pesticide and resulted in the Agency providing the company with revised lists of data requirements, first determining that Castor Oil (USP) was a **biochemical** and later determining that it was a **Reduced Data Active Ingredient.**

Reasons for One Year, Unconditional Registration

Normally, the Agency registers a new active ingredient after it has received all the required data and has made several findings under section 3(c)(5) concerning acceptable composition, claims, efficacy, and labeling and after balancing risks and benefits. However, even though the Agency has no risk concerns, it cannot make the final determinations required under the Statute without the efficacy data. I am proposing to allow an unconditional registration for a period of **one** year, which is a reasonable amount of time for the registrant to generate and submit acceptable data to the Agency.

Pending Regulatory Action

Prior to applying for registration in December 1990, the registrant was selling this product illegally throughout the country, resulting in fines placed on the registrant for such activities. The Justice Department, who has authority to collect these fines, has not given this case priority. Therefore, this enforcement case is still pending.

Regulatory Status

The enforcement action against the registrant, for selling an unregistered pesticide, is still pending.

The data base for the Reduced Data Active Ingredient, Castor Oil (USP Grade) and its end-use product, Mole-Med, is complete, **except** for efficacy data. In addition, the Agency has no risk concerns about the active or its end-use. Finally, the Agency will make a **final** decision about the registration of Mole-Med under section 3(c)(5), within one year.

This approach will allow sufficient time to receive and review the efficacy data expected later this summer and to request additional information from the Company if needed. Depending upon our review of these data, the Agency will either continue the registration or cancel it automatically, without a hearing.

RECOMMENDATION

I am recommending that you **concur** with the Agency's unconditional, one-year registration of Mole-Med.

Concur: _____

Do Not Concur: _____

Date: 8/1/94